IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

PFIZER INC, PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC, Plaintiffs, v. MYLAN INC., MATRIX LABORATORIES LIMITED, and MATRIX LABORATORIES INC., Defendants	)	Civil Action No. 1:09-CV-79

COMPLAINT

Pfizer Inc, Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively referred to as "Pfizer"), by their attorneys, for their Complaint against Mylan Inc., Matrix Laboratories Limited, and Matrix Laboratories Inc. (collectively "Defendants"), allege as follows:

1. This is an action by Pfizer against Defendants for infringement of U.S. Patent No. 5,969,156 and its Reexamination Certificate (collectively "the '156 patent"); U.S. Patent No. 6,087,511 ("the '511 patent"); and U.S. Patent No. 6,274,740 ("the '740 patent") (collectively "the patents in suit"). A copy of the '156 patent with the '156 Reexamination Certificate is attached hereto as Exhibit A. A copy of the '511 patent is attached hereto as Exhibit B. A copy of the '740 patent is attached hereto as Exhibit C.

PATENTS IN SUIT

2. On October 19, 1999, the United States Patent and Trademark Office (USPTO) issued the '156 patent, entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)-ß,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid) Hemicalcium Salt (Atorvastatin)", on an application filed by Christopher Briggs, *et al.*, and assigned to Warner-Lambert Company. On September 26, 2006, the USPTO issued an Ex Parte Reexamination Certificate for the '156 patent.

3. On July 11, 2000, the USPTO issued the '511 patent, entitled "Process for the Production of Amorphous [R-(R*,R*)]-2-(4-Fluorophenyl)-ß,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid) Calcium Salt (2: 1)", on an application filed by Min Lin, *et al.*, and assigned to Warner-Lambert Company.

4. On August 14, 2001, the USPTO issued the '740 patent, entitled "Process for the Production of Amorphous [R-(R*,R*)]-2-(4-Fluorophenyl)-ß,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid Calcium Salt (2: 1)", on an application filed by Min Lin, *et al.*, and assigned to Warner-Lambert Company.

PARTIES, JURISDICTION AND VENUE

5. Pfizer Inc is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

6. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the patents in suit since their issuance.

7. Warner-Lambert Company became a wholly owned subsidiary of Pfizer Inc effective June 19, 2000.

8. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.

9. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

10. The exclusive licensee of the patents in suit is Pfizer Ireland Pharmaceuticals.

11. Pfizer has all the right, title, and interest in the patents in suit and the right to sue for infringement thereof.

12. Pfizer holds an approved New Drug Application for an atorvastatin calcium formulation which it sells under the registered name Lipitor®.

13. The ‘156 patent is identified pursuant to 21 U.S.C. §355(b)(1) by the United States Food and Drug Administration (“FDA”) as covering Pfizer’s Lipitor® product.

14. On information and belief, Defendant Mylan Inc. (“Mylan”) is a corporation operating and existing under the laws of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg PA 15317 and a place of business at White Birch Tower II, 5th Floor, 1311 Pineview Drive, Morgantown WV 26505.

15. On information and belief, Defendant Matrix Laboratories Limited (“Matrix Ltd.”) is a sister corporation of Mylan and is wholly-owned or controlled by Mylan, and is a corporation operating and existing under the laws of India with its principal place of business at

1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad - 500 003, Andhra, Pradesh, India. On information and belief, Matrix Ltd. does not reside, have a place of business, or have a continuous or systematic presence within the United States.

16. On information and belief, Defendant Matrix Laboratories Inc. ("Matrix Inc.") is the United States agent of Matrix Ltd. and/or is a sister corporation of Mylan and is wholly-owned or controlled by Mylan, and is a corporation operating and existing under the laws of the State of Delaware with a principal place of business at 76 South Orange Ave., Suite 301, South Orange NJ 07079.

17. On information and belief, Mylan and/or Matrix Ltd. and/or Matrix Inc. filed with the FDA, in Rockville, Maryland, ANDA No. 91-226 under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, which are generic versions of Pfizer's Lipitor® tablets.

18. By its letter dated May 1, 2009, Mylan notified Pfizer that Matrix Ltd. had filed an ANDA seeking FDA approval to market atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, and that it was providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(a). The May 1, 2009 letter did not specify an agent authorized to accept service of process for Matrix Ltd. as required by 21 CFR § 314.95(c)(7). A copy of the May 1, 2009 letter to Pfizer is attached hereto as Exhibit D.

19. The May 1, 2009 letter purported to contain an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C).

20. The purported "Offer of Confidential Access to Application" contained restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355(j)(5)(C)(III).

21. The May 1, 2009 letter addressed the '156 patent and asserted that the patent was invalid and/or not infringed by Defendants' proposed ANDA No. 91-226 atorvastatin calcium product.

22. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

23. Mylan has offices located in West Virginia and is subject to personal jurisdiction in this District.

24. On information and belief, Matrix Ltd. is subject to personal jurisdiction in this District.

25. On information and belief, Matrix Inc. is subject to personal jurisdiction in this District.

26. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

27. On information and belief, Defendants are in the business of developing and manufacturing generic pharmaceutical products.

28. On information and belief, Mylan is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Matrix Ltd. and/or Matrix Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of West Virginia.

29. On information and belief, Mylan, as the authorized agent of Matrix Ltd. and/or Matrix Inc., and/or in its own capacity, participated in the preparation and filing with the FDA of the Matrix Ltd. ANDA 91-226 for approval to market generic atorvastatin calcium in the United States.

30. On information and belief, Matrix Ltd. and/or Matrix Inc. develops and manufactures generic drugs and, directly or indirectly through Mylan, markets, distributes, and sells its generic drugs throughout the United States, including the State of West Virginia.

31. Personal jurisdiction over Mylan is proper because Mylan has offices in West Virginia and has purposely availed itself of the privilege of doing business in this State. Further, Mylan maintains continuous and systematic contacts with the State of West Virginia so as to reasonably allow jurisdiction to be exercised over it.

32. Personal jurisdiction over Matrix Ltd. is proper, *inter alia*, because it purposefully avails itself of the privilege of selling its generic products in the State of West Virginia and can therefore reasonably expect to be subject to jurisdiction in Courts in West Virginia. Among other things, on information and belief, Matrix Ltd. directly or through its sister corporations Matrix Inc. and/or Mylan, places goods into the stream of commerce for distribution throughout the United States, including the State of West Virginia.

33. Personal jurisdiction over Matrix Inc. is proper, *inter alia*, because it purposefully avails itself of the privilege of selling its generic products in the State of West Virginia and can therefore reasonably expect to be subject to jurisdiction in Courts in West Virginia. Among other things, on information and belief, Matrix Inc. directly or through its sister corporations Matrix Ltd. and/or Mylan, places goods into the stream of commerce for distribution throughout the United States, including the State of West Virginia.

FIRST CLAIM FOR RELIEF:
INFRINGEMENT OF THE '156 PATENT

34. The allegations of paragraphs 1-33 above are repeated and realleged as if set forth fully herein.

35. Pfizer has received a letter dated May 1, 2009 from Mylan which notified Pfizer that Defendants had filed a ANDA No. 91-226, seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium prior to the expiration of the '156 patent.

36. The expiration date for the '156 patent is July 8, 2016.

37. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to January 8, 2017.

38. Defendants have infringed the '156 patent under 35 U.S.C. § 271(e)(2)(A) by filing their ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium prior to the expiration of the '156 patent.

39. Pfizer will be irreparably harmed if Defendants' ANDA No. 91-226 is approved prior to the expiration date of the '156 patent.

40. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '156 patent.

SECOND CLAIM FOR RELIEF:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '511 PATENT

41. The allegations of paragraphs 1-40 above are repeated and realleged as if set forth fully herein.

42. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and

active steps to obtain FDA permission to sell in the United States and, after obtaining FDA permission, to commence sale in the United States of Defendants' atorvastatin calcium product before the expiration date of the '511 patent. There is a real and actual controversy between the parties respecting Defendants' activities and infringement of the '511 patent.

43. The expiration date for the '511 patent is July 16, 2016.

44. The '511 patent covers a method of making amorphous atorvastatin calcium.

45. In the May 1, 2009 letter to Pfizer, Defendants disclosed the process of making their atorvastatin calcium product that is the subject of ANDA No. 91-226. This process utilized a crystalline atorvastatin calcium intermediate which is then processed into a final allegedly amorphous atorvastatin calcium product.

46. On information and belief, the process for making Defendants' atorvastatin calcium product has been and will be carried out outside of the United States.

47. Accordingly, on information and belief, by seeking FDA approval for the atorvastatin calcium product as described in Defendants' May 1, 2009 letter, Defendants intend to import into the United States and/or to offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), an atorvastatin calcium product that is made by a process which if practiced in the United States would infringe the '511 patent.

48. On information and belief, Defendants' importation (either individually or collectively) for purposes not exempt under 35 U.S.C. § 271(e)(1) into the United States and/or future offer to sell, sale, or use for purposes not exempt under 35 U.S.C. § 271(e)(1) within the United States the atorvastatin calcium product that is the subject of ANDA No. 91-226 will infringe the '511 patent pursuant to 35 U.S.C. § 271(g).

49. Alternatively, in the event that Defendants carry out their process for making their atorvastatin calcium product in the United States, the carrying out of the process and the use and/or sale of the resulting product will infringe the '511 patent pursuant to 35 U.S.C. §§ 271(a) and (g).

50. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '511 patent.

THIRD CLAIM FOR RELIEF:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '740 PATENT

51. The allegations of paragraphs 1-50 above are repeated and realleged as if set forth fully herein.

52. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps to obtain FDA permission to sell in the United States and, after obtaining FDA permission, to commence sale in the United States of Defendants' atorvastatin calcium product before the expiration date of the '740 patent. There is a real and actual controversy between the parties respecting Defendants' activities and infringement of the '740 patent.

53. The expiration date for the '740 patent is July 16, 2016.

54. The '740 patent covers a method of making amorphous atorvastatin calcium.

55. In the May 1, 2009 letter to Pfizer, Defendants disclosed the process of making their atorvastatin calcium product that is the subject of ANDA No. 91-226. This process utilized a crystalline atorvastatin calcium intermediate which is then processed into a final allegedly amorphous atorvastatin calcium product.

56. On information and belief, the process for making Defendants' atorvastatin calcium product has been and will be carried out outside of the United States.

57. Accordingly, on information and belief, by seeking FDA approval for the atorvastatin calcium product as described in Defendants' May 1, 2009 letter, Defendants intend to import into the United States and/or to offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), an atorvastatin calcium product that is made by a process which if practiced in the United States would infringe the '740 patent.

58. On information and belief, Defendants' importation (either individually or collectively) for purposes not exempt under 35 U.S.C. § 271(e)(1) into the United States and/or future offer to sell, sale, or use for purposes not exempt under 35 U.S.C. § 271(e)(1) within the United States the atorvastatin calcium product that is the subject of ANDA No. 91-226 will infringe the '740 patent pursuant to 35 U.S.C. § 271(g).

59. Alternatively, in the event that Defendants carry out their process for making their atorvastatin calcium product in the United States, the carrying out of the process and the use and/or sale of the resulting product will infringe the '740 patent pursuant to 35 U.S.C. §§ 271(a) and (g).

60. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '740 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval for Defendants' ANDA No. 91-226 be no earlier than January 8, 2017, the date of expiration of the '156 Patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Defendants' ANDA No. 91-226 until January 8, 2017, the expiration date of the '156 patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

C. A declaratory judgment that Defendants' atorvastatin calcium product that is the subject of ANDA No. 91-226 is made and will be made by the processes claimed in the '511 and/or the '740 patents and that the importation of that product into the United States and its offer for sale, sale, and/or use in the United States, regardless of where made, is an infringement of one or both of the '511 and '740 patents;

D. A judgment permanently enjoining Defendants from infringing the processes claimed in the '511 and/or '740 patents to the extent the processes are carried out in the United States;

E. A judgment permanently enjoining Defendants from using, selling, offering to sell, or importing the atorvastatin calcium product that is the subject of ANDA No. 91-226 when made by a process claimed in the '511 and/or '740 patents until July 16, 2016, the expiration date of the '511 and '740 patents;

F. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such further and other relief as this Court may deem just and proper.

PFIZER INC.,
PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY, and
WARNER-LAMBERT COMPANY LLC, Plaintiffs

By /s/ James F. Companion
Of Counsel

James F. Companion (WV Bar #790)
E-mail: jfc@schraderlaw.com
John Porco (WV Bar #6946)
E-mail: jp@schraderlaw.com
SCHRADER BYRD & COMPANION, PLLC
The Maxwell Centre
32-20th Street, Suite 500
Wheeling, WV 26003
Telephone: (304) 233-3390
Facsimile: (304) 233-2769

Rudolf E. Hutz (subject to admission *pro hac vice*)
Jeffery B. Bove (subject to admission *pro hac vice*)
Mary W. Bourke (subject to admission *pro hac vice*)
Daniel C. Mulveny (subject to admission *pro hac vice*)
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207
Telephone: (302) 658-9141
Facsimile: (302) 658-5614

William E. McShane (subject to admission *pro hac vice*)
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
Telephone: (202) 572-0335

Dated: June 15, 2009
692614_1.DOC